ISRCTN58708001 https://doi.org/10.1186/ISRCTN58708001

Dyslipidemia in Japanese Patients with Rheumatoid Arthritis

Submission date	Recruitment status	[ ] Prospectively registered
02/06/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/06/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/06/2010	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Taro Mawatari

Contact details
Maidashi 3-1-1
Higashi-ku
Fukuoka
Japan
812-8582

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Dyslipidemia in Japanese Patients with Rheumatoid Arthritis: A Retrospective Multicentre Observational Study

Study objectives
By investigating the prevalence of dyslipidemia and its relationships with disease activity, or medical interventions, it is possible to reduce subsequent mortality and morbidity of cardiovascular disease in patients with rheumatoid arthritis (RA).

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Institutional Review Board of the Kyushu University School of Medicine approved on the 10th of May 2010

Study design
Retrospective multicentre observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Rheumatoid arthritis

Interventions
Non-interventional, observational study.
The blood samples from a cohort of patients being treated with lipid-lowering drugs will be taken at baseline, 2, 4, 6, 8 months after administration.
Information will be collected on the patient's history of cardiovascular events.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

1. To investigate the lipid profile and estimate the prevalence of dyslipidemia
2. To determine the relationships between the lipid profiles and the RA disease activity, or the treatments such as Disease Modifying Antirheumatic Drugs (DMARDs), biologics, glucocorticoids.

Secondary outcome measures
To investigate the effect of administered statins in the treatment of dyslipidemia in Japanese patients with RA.

Overall study start date
01/06/2009

Completion date
31/03/2013

Eligibility

Key inclusion criteria
1. Age > 18 yrs
2. Fulfilled the 1987 revised criteria for RA of the American College of Rheumatology
3. Access to medical record information

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
500

Key exclusion criteria
History of medical conditions other than RA which may affect lipid profile

Date of first enrolment
01/06/2009

Date of final enrolment
31/03/2013

Locations

Countries of recruitment
Japan

Study participating centre
Maidashi 3-1-1
Fukuoka
Japan
812-8582

Sponsor information

Organisation
Kyushu University (Japan)

Sponsor details
Department of Orthopaedic Surgery
Graduate School of Medical Sciences
Maidashi 3-1-1
Higashi-ku
Fukuoka
Japan
812-8582

Sponsor type
University/education

ROR
https://ror.org/00p4k0j84

Funder(s)

Funder type
University/education

Funder Name
Graduate School of Medical Sciences, Kyushu University (Japan) - Department of Orthopaedic Surgery

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration